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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/633,180	08/04/2000	Mitchell Anthony DeLong	8191	2275

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THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION
WINTON HILL TECHNICAL CENTER - BOX 161
6110 CENTER HILL AVENUE
CINCINNATI, OH 45224

EXAMINER

WRIGHT, SONYA N

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 06/05/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/633,180

Applicant(s)

DELONG, MITCHELL ANTHONY

Examiner

Sonya Wright

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 34-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-37 are pending in this application.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-33 and the derivatives of prostaglandin E as defined in Claim 29 in Paper No. 9 is acknowledged. Applicant is correct in assuming that Group I was intended to be drawn to Claims 1-33 (instead of 1-37 as set forth in the restriction requirement). Due to the species election, the examination has been limited to the compounds of claim 29. All other subject matter in claims 1-33 and the subject matter in claims 34-50 in their entirety has been withdrawn from consideration as being drawn to a non-elected invention.

Claims 1-33 are objected to for containing non-elected subject matter. It is requested that Applicant limit the claims to the subject matter of claim 29.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Aristoff et al., AN: 1982:406057. Applicant teaches prostaglandin compounds which are useful in inhibiting gastric acid secretion. Aristoff et al. teach prostaglandin compounds that are useful in reducing gastric secretion. Aristoff et al. disclose intermediate species RN

76794-01-9 which is a species of the first compound in instant claim 29, wherein "a" is a double bond.

Claims 1-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Biddlecom et al. , US Patent 4,171,331. The compounds of Biddlecom et al. are useful in inhibiting gastric secretion. Biddlecom et al. teach species examples of the claimed compounds. See Example V, column 29 lines 58-66 and column 30, lines 1-12; Example IX, column 32, lines 60-66 and column 33, lines 1-9. Note that these are species of the second compound of instant claim 29, wherein "a" is a double bond.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biddlecom et al, US Patent 4,171,331. Applicant teaches compounds which are useful in inhibiting gastric acid secretion.

Determination of the scope and content of the prior art (MPEP §2141.01)

The compounds of Biddlecom et al. are useful in inhibiting gastric secretion. Biddlecom et al. teach species examples of the claimed compounds. See Example V, column 29 lines 58-66 and column 30, lines 1-12; Example IX, column 32, lines 60-66 and column 33, lines 1-9. Note that these are species of the second compound of instant claim 29, wherein "a" is a double bond. Biddlecom et al. generically teach the instant compounds in column 7, lines 34-67 and column 8, lines 1-21.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between Biddlecom et al. and the instant claims is that Biddlecom et al. generically teach the instant compounds in column 7, lines 34-67 and column 8, lines 1-21.

Finding of prima facie obviousness---rational and motivation (MPEP §2142-2143)

The indiscriminate selection of "some" among "many" is prima facie obvious. One of ordinary skill in the art would be motivated to prepare the instant compounds because of the species examples of the instantly claimed compounds in Biddlecom et al. See Example V, column 29 lines 58-66 and column 30, lines 1-12; and Example IX, column 32, lines 60-66 and column 33, lines 1-9. It is expected that structurally similar compounds would possess similar activity (i.e. treating gastric secretion).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1-33 contain the term "2-decarboxy-2-

phosphinico prostaglandin derivative" or "derivative". The specification does not reasonably provide enablement for the instantly claimed compounds.

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. The prior art does not indicate which "derivatives" may be useful in the claimed invention. There is little predictability in the art of which modifications may be made to the claimed compound which would retain it's ability to be useful in treating bone disorders, vascular diseases, skin conditions, and sexual dysfunction. The term "derivative" may encompass a great number of compounds however, without some guidance as to what changes may be made to the compounds of claim I, there would be little predictability in making and/or using such "derivative". The level of ordinary skill in the art is high. In terms of guidance, the limited guidance of pages 40-90 lacks sufficient enablement for the claimed scope. Therefore, based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not operate the method as claimed without undue experimentation.

This rejection can be overcome by Applicant replacing the term "derivative" with the term —compound— in all occurrences.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 contains the terms "biohydrolyzable amide", "biohydrolyzable ester", "biohydrolyzable imide", and "salt" of the structure. The terms are ambiguous and self-conflicting. The scope that is encompassed by these terms is not clear. Is the salt an "addition" salt of an acid or base compound of the claims? Is the salt part of the Markush element? Is the hydrolyzable ester a precursor that can be hydrolyzed into one of the Markush compounds or is it a Markush member to be hydrolyzed?

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for

draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.



Celia Chang

Primary Examiner

Group 1600

Sonya Wright

May 30, 2002